Health Technology Assessment in Canada And the United States: the Case of Biologics

Canadian health technology assessments (HTAs) are coordinated by government agencies, while HTA activity in the United States is conducted haphazardly by a variety of interest groups. As a result, biologic therapies have diffused more slowly and rationally in Canada, according to the authors. If HTAs were conducted similarly in the United States, the distribution of biologics might occur more efficiently.

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Health technology is broadly defined to include drugs, medical devices and procedures, and support and organizational systems (Perry 1997a). A health technology assessment (HTA) evaluates the safety, efficacy, cost and cost-effectiveness, and legal and ethical implications of a new technology. It also uses those indices to determine the overall value of that technology in absolute terms, as well as to compare it with an existing or competing technology (Garcia-Altes 2004).

The need for HTAs revolves around finding a balance between two competing challenges healthcare providers face. Clinicians must offer their patients the most current care options available, while taking into account which one provides the best use of limited resources (Barnett 2002). Safety, efficacy, ethics, and legal implications of new technologies must be assessed to predict patient outcomes. Because new technology is a major driving force behind increasing healthcare costs (Becker 2003), a cost-effectiveness analysis is critical to determine how to efficiently spend healthcare dollars.

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HTA also is a crucial link between introducing a new health technology into the marketplace and integrating it into clinical practice. As a new technology is developed, evidence must be provided to obtain a license. However, the evidence needed for licensing has little in common with the evidence used to support clinical practice. A major goal of an HTA is to bridge this gap and ensure that clinical decisions are as evidence-based as possible (Barnett 2002).

As the rate of new scientific advances increases, an HTA takes on greater importance. Part of the growth in technological discoveries stems from more activity by university technology transfer offices, which assist faculty in the development, marketing, and implementation of new technologies and techniques. Data have shown a steady growth between 1996 and 2002 in the number of patent applications, licenses, and options that originated from technology transfer offices (Fleischut 2005). As more resources are devoted to the development of new technologies, more effort must be made to properly evaluate them.

The field of HTA has grown since organizations devoted to it gained

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support in the 1970s and 1980s (Perry 1997a, Garcia-Altes 2004). Whereas Canada has devoted significant resources to the creation of centralized, government-run HTA agencies, the growth of HTA in the United States has been largely restricted to the private sector (Garcia-Altes 2004, Perry 1997b). The lack of a centralized HTA system has led to the fragmentation, overlap, and haphazard diffusion of new technology along with wasted resources (Perry 1997b). This article discusses how the assessment of biologics is conducted in both countries, and proposes how biologics would diffuse in the United States if a central HTA system existed.

HTA SYSTEMS IN CANADA AND THE UNITED STATES

The majority of HTA activity in Canada originates from four government-operated agencies: the Conseil d'Évaluation des Technologies de la Santé du Québec (CETS); the Canadian Coordinating Office for Health Technology Assessment (CCOHTA); the British Columbia Office of Health Technology Assessment (BCOHTA); and the Health Technology Assessment Unit of the Alberta Heritage Foundation for Medical Research (AHFMR). Other agencies, such as the Calgary Health Technology Implementation Unit (CaHTIU), along with hospitals, per-

TABLE 1
Sources of health technology assessment in Canada

HTA source (year founded)	Mission	Reports apply	Unique attributes
CETS (1988)	Foster and support HTA; provide advice to government on how new technology should be introduced, diffused, and utilized	Nationally Provincially	Makes stronger efforts than other government agencies to affect decision makers
CCOHTA (1989)	Inform decision makers about medical technologies, and coordinate and support HTA activity in Canada	Nationally	Exclusively national focus
BCOHTA (1990)	Sponsor and promote HTA on three levels: governmental, clinical, and operational	Nationally Provincially	Rarely incorporates cost elements in its reports
AHFMR (1996)	Provide HTA activity more relevant to Alberta	Nationally Provincially	Founded with the goal of addressing HTA on a provincial level
CaHTIU (1997)	Address the unique needs of HTA within the Calgary Health region	Regionally Locally	Possesses a regional focus, works to implement recommendations from HTA studies, and collaborates with academia
Hospital-based organizations	Study technology that is most pertinent to their specific patient populations	Locally	Can implement findings rapidly and affect decision makers

AHFMR=Health Technology Assessment Unit of the Alberta Heritage Foundation for Medical Research, BCOHTA=British Columbia Office of Health Technology Assessment, CaHTIU=Calgary Health Technology Implementation Unit, CCOHTA=Canadian Coordinating Office for Health Technology Assessment, CETS=Conseil d'Évaluation des Technologies de la Santé du Québec, HTA=Health Technology Assessment.

SOURCES: JUZWISHIN 1996, LEE 2003, MENON 2000

form regionally and locally focused HTA (Table 1).

Although HTA in the United States was originally and largely conducted by government agencies, national efforts have decreased as these organizations have evolved (Figure). Opposition to government HTA activity stemmed from physicians and drug and device manufacturers. The former believed their autonomy was threatened and argued that they alone can make the best decisions for their patients, as they have done for decades (Eisenberg 2002). Drug and device manufacturers have financial interests in keeping the status quo, as slower product diffusion into the marketplace would have a negative impact on their profits.

In contrast to federal HTA activity, the growth of HTA organizations within the private sector has been consistent and significant. Several professional medical societies cooperated with the Blue Cross/Blue Shield Association to organize the Medical Necessity Project in 1976, the objectives of which were to identify obsolete procedures and tests and to improve healthcare quality. Since then, academic medical centers, insurance companies, HMOs, professional societies, hospitals, private consulting firms, and the drug and device industry all have sponsored HTA activity. However, the structure, procedures, and goals of each of these organizations differ greatly from one another. As such, HTA in the United States is quite fragmented and repetitive (Perry 1997b).

DISCUSSION

The differences in HTA systems in the United States and Canada are systemic (Table 2, page 50). In Canada, the HTA of biologic therapies (as well as diagnostics and devices) is centralized, and all relevant information on efficacy, safety, and cost-effectiveness is found easily in a report from one of the government-operated agencies.

In the United States, many researchers at different institutions contribute to the HTA of biologics, but their efforts occur haphazardly. With no central location for HTA reports, healthcare providers rely on literature searches to gather data. In peer-reviewed journals, there is little consistency in publishing studies that address safety, efficacy, cost, or cost-effectiveness — alone or in combination — of biologics.

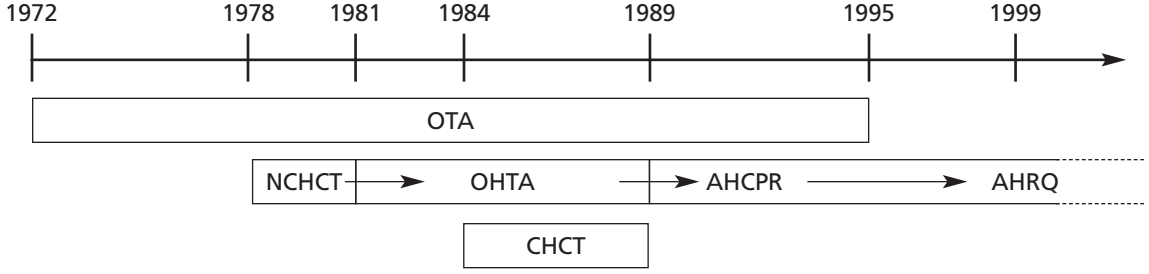
If the United States had a centralized HTA system, biologic assessments would be dramatically different. Fewer repetitive analyses, perhaps, would be the most striking change. Many papers are published by researchers within such a close timeline that investigators often conduct studies simultaneously. A system of coordinated HTA efforts would likely reduce overlapping projects, allowing study conclusions to be distributed and utilized more efficiently by researchers.

This degree of repetition also burdens decision makers when deter-

FIGURE

Time line and evolution of U.S. health technology assessment organizations

Arrows indicate the flow of organizations that have advised the Health Care Financing Administration/ Centers for Medicare & Medicaid Services.



AHCPR=Agency for Health Care Policy and Research, AHRQ=Agency for Healthcare Research and Quality, CHCT=Council on Health Care Technology, NCHCT=National Center for Health Care Technology, OHTA=Office of Health Technology Assessment, OTA=Office of Technology Assessment.

SOURCE: EISENBERG 2002

mining whether to adopt a new technology. For every published study, readers must seek it out, evaluate its methodology, verify the validity of cited sources, and judge the conclusions. Much effort is required to fully scrutinize the literature published on a new health technology.

One benefit of a centralized system is the collection of information regarding all features of a new technology in one location, regardless of the number of repetitive studies. In the United States, different features of biologics are published in different and multiple sources. The time required to assemble the entire HTA picture of a biologic can be reduced with a central, coordinated system, which would then present an objective synthesis of all pertinent research. If it were found that more caution should be urged before using a specific therapy, perhaps biologics would diffuse more appropriately.

The potential benefits of a central HTA system are not difficult to envision, nor are they recent revelations. Proponents of such a process have argued their case for decades (Perry 1997b). The question then becomes obvious — why has the United States been unable to support and maintain such a system? The answer isn't surprising, as it includes many of the same reasons as to why the U.S. healthcare system has yet to take full advantage of available technology to standardize and simplify the process of storing, transferring, and retrieving patient information (Reynolds 2003).

As with any project with national implications, government and politics play major roles. Legislators often face pressure from lobbyists when attempting to create any measure that seriously conflicts with group interests. In the past, when acting on behalf of physicians and drug and device manufacturers, lobbyists have fought government HTA organizations. Fears of political overinvolvement in the decision-making process also have delayed the creation of a new national HTA organization (Howell 2003).

The lack of a national healthcare system also partly explains the absence of a central HTA system. In the United States, health services are provided mainly under the influence of private organizations with competing interests. There is little synchrony among the agendas of the different sectors (e.g., payers, providers, and manufacturers) of the U.S. healthcare system, and standardizing the assessment processes to evaluate technology becomes very difficult (Reynolds 2003, Perry 1997b).

Standardization also is impeded by U.S. social norms. American citizens simply are not used to the idea of a national *anything* when it comes

TABLE 2
Differences in health technology assessment in the United States and Canada

	United States	Canada
Structure	Fragmented	Centralized and coordinated
Major sources of assessments	Academia/independent researchers Health insurers Professional organizations Federal/state organizations Hospitals Consulting firms Drug and device manufacturers	National government agencies Provincial government agencies Regional government agencies Hospitals
Duplication	Significant	Negligible
Cost considerations included in assessments	Less common	More common
Primary method of disseminating findings	Peer-reviewed journals	Freestanding reports

SOURCES: EISENBERG 2002, GARCIA-ALTES 2004, JUZWISHIN 1996, LEE 2003, MENON 2000, PERRY 1997B

to the healthcare system. It is likely that most people do not understand the potential benefits of standardization because they have no experiences to draw upon (Reynolds 2003). Further, patients are used to demanding — and receiving — the newest technology as soon as it is available. Any system that reduces patients' options would require a dramatic shift in societal expectations (Howell 2003).

One issue that must be considered is cost, which can be prohibitive when trying to enable systematic change. Some have suggested an income tax as the best means for funding a national HTA project. The specter of voter disapproval makes it unlikely that Congress would approve such a measure, however. Proposing to place the burden on insurers would be certain to induce heavy lobbying to the contrary (Howell 2003).

Competing business and professional interests, political considerations, and lack of public support of a national *anything* when it comes to healthcare preclude a U.S. HTA system.

FUTURE DIRECTIONS

Forming a national HTA system to promote appropriate diffusion of new health technology presents many challenges. According to industry experts, nearly all stakeholders would have to agree on its need before such a system could be created. The government's role would have to be limited to providing the resources for the national effort — not to interpreting the findings reached by the national organization, nor to deciding which technologies the insurers would be required to cover. The issue of how to pay for the new system would also need to be addressed (Howell 2003).

Beyond the HTA system itself, other factors influence the diffusion of new health technology. The willingness of healthcare administrators and physicians to accept HTA recommendations and patient demand factor into this process, as do measures to increase the effect of HTA reports (Hivon 2005, McGregor 2005, Howell 2003, Eisenberg 2002).

Despite numerous barriers, all of these have a central commonality: culture. The HTA system in the United States reflects the nation's culture, characterized by private organizations, competing interest groups, and autonomous individuals. American culture drives the fragmented evolution of the HTA system and is the overarching reason why the system remaines decentralized, even with a continued and recognized need for national coordination. Without a fundamental cultural shift, efforts to sustain a central HTA system in the United States will continue to fall short.

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DISCLOSURES

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